



Virginia
Regulatory
Town Hall

Emergency Regulation Agency Background Document

Agency Name:	Department of Health
VAC Chapter Number:	12 VAC 5-90-80
Regulation Title:	Regulations for Disease Reporting and Control
Action Title:	Add 'Vaccinia, Disease or Adverse Event' to the Reportable Disease List
Date:	February 7, 2003

Section 9-6.14:4.1(C)(5) of the Administrative Process Act allows for the adoption of emergency regulations. Please refer to the APA, Executive Order Twenty-Four (98), and the *Virginia Register Form, Style and Procedure Manual* for more information and other materials required to be submitted in the emergency regulation submission package.

Emergency Preamble

Please provide a statement that the emergency regulation is necessary and provide detail of the nature of the emergency. Section 9-6.14:4.1(C)(5) of the Administrative Process Act states that an "emergency situation" means: (i) a situation involving an imminent threat to public health or safety; or (ii) a situation in which Virginia statutory law, the Virginia appropriation act, or federal law requires that a regulation shall be effective in 280 days or less from its enactment, or in which federal regulation requires a regulation to take effect no later than 280 days from its effective date. The statement should also identify that the regulation is not otherwise exempt under the provisions of § 9-6.14:4.1(C)(4).

Please include a brief summary of the emergency action. There is no need to state each provision or amendment.

This emergency regulation is necessary due to an imminent threat to public health. Smallpox vaccinations have already begun in Virginia, and some adverse reactions to the vaccine are expected. Vaccinia is the virus that is in the smallpox vaccine. This virus can cause serious and life-threatening disease in vaccine recipients and their contacts. The emergency action amends 12 VAC 5-90-80, the reportable disease list from the Regulations for Disease Reporting and Control, to add "Vaccinia, disease or adverse event" to the list, thereby making this a reportable condition in Virginia and allowing the Virginia Department of Health to track and respond to smallpox vaccine reactions.

Basis

Please identify the state and/or federal source of legal authority to promulgate the emergency regulation. The discussion of this emergency statutory authority should: 1) describe its scope; and 2) include a brief statement relating the content of the statutory authority to the specific regulation. Full citations of legal authority and web site addresses, if available for locating the text of the cited authority, should be provided.

Please provide a statement that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the emergency regulation and that it comports with applicable state and/or federal law.

Authority exists under 2.2-4011 of the Code of Virginia in that a situation exists involving an imminent threat to public health. Smallpox vaccinations are starting to occur across Virginia, for the first time in over 30 years. Because this vaccine has not been given in recent decades and the health of the American population has changed in these intervening years, the Virginia Department of Health does not know what level of adverse reactions to expect among vaccine recipients and their contacts. A method of tracking reactions to the vaccine is needed. Vaccinia is the virus that is in the smallpox vaccine, and this action would require physicians and directors of medical care facilities to report illness caused by this virus among people receiving the vaccine or their contacts. This provides information to the Department regarding the numbers and types of reactions being experienced by persons receiving the vaccine and their contacts and ensures that those experiencing reactions receive appropriate therapy to treat the event.

Substance

Please detail any changes, other than strictly editorial changes, that would be implemented. Please outline new substantive provisions, all substantive changes to existing sections, or both where appropriate. Please provide a cross-walk which includes citations to the specific sections of an existing regulation being amended and explain the consequences of the proposed changes. The statement should set forth the specific reasons the agency has determined that the proposed regulatory action would be essential to protect the health, safety or welfare of Virginians. The statement should also delineate any potential issues that may need to be addressed as a permanent final regulation is developed.

The emergency action amends 12 VAC 5-90-80, the reportable disease list from the Regulations for Disease Reporting and Control, to add “Vaccinia, disease or adverse event” to the list, thereby making this a reportable condition in Virginia. The reportable disease list is the mechanism used by the Virginia Department of Health to gather information about conditions affecting the health of citizens of the Commonwealth. This regulatory action will position the Department to monitor reactions resulting from the smallpox vaccination program and ensure that measures are taken to protect the health of those so affected. That program is part of Virginia’s preparedness efforts for bioterrorism response.

Alternatives

Please describe the specific alternatives that were considered and the rationale used by the agency to select the least burdensome or intrusive method to meet the essential purpose of the action.

An alternative that was considered was to request that physicians report reactions to the national Vaccine Adverse Events Reporting System. That method would bypass the local and state health departments and risk that information would not be available to the Virginia Department of Health about adverse events affecting the health of citizens of Virginia. Declaring vaccinia disease and vaccinia adverse events as reportable ensures that information about reactions to the smallpox vaccine is brought to the attention of the Department. The Department will, in turn, ensure that appropriate treatments and precautions are instituted in response to the disease event.

Family Impact Statement

Please provide a preliminary analysis of the potential impact of the emergency action on the institution of the family and family stability including to what extent the action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

No longer required by executive order.